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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,741	10/17/2001	Matthew T. Scholz	54402US028	7855

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EXAMINER	
EGAN, BRIAN P	

ART UNIT	PAPER NUMBER
1772	19

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,741	SCHOLZ ET AL.	
	Examiner	Art Unit	
	Brian P. Egan	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-20, 23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5-10, 19-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al. (#5,948,707) in view of WO 97/27775 (hereinafter WO '775) and Lindquist et al. (#3,738,359).

Crawley et al. teach a medical drape (Col. 5, line 6) comprising a backing layer having a first surface and a second surface (Fig. 1, #12), where projecting from the first surface of the backing layer is an array of stems (Fig. 1, #15; Col. 4, lines 5-13), wherein at least a portion of the exterior surface of the stems comprises a thermoplastic elastomeric material (Col. 8, lines 15-17). The stems of the drape are generally upstanding and have a static coefficient of friction of at least 0.6 (Col. 3, lines 49-57). Crawley et al. do not explicitly state that the stems have a coefficient of friction within 20% of 0.6 when wet although this limitation is inherently met given that the material limitations have been met by the reference. The medical drape further comprises a second backing layer adjacent to the second surface of the first backing layer (Fig. 1, #16) where projecting from the second backing layer is a second array of stems, the second array of stems comprising an elastomeric material (Col. 8, lines 44-47). The density of the stems on the first surface of the backing layer is at least 15.5 stems/cm^2 (See Example 2; given a diameter of 0.53mm and the fact that the stems can be distributed to cover 5-95% of the surface area (Col.

7, lines 11-15), 15.5 stems/cm2 would only cover 3.47% of the surface area (radius = 2.65mm, π x 2.65^2 x 15.5 stems = 3.417mm^2 = 0.03417cm^2, 0.03417 x 100 = 3.417% of surface area covered with 15.5 stems) therefore, to cover at least 5% of the surface area, there will have to be more than 15.5 stems/cm^2). The elastomeric material comprises silicon rubber (Col. 8, lines 17-19). Although Crawley et al. do not explicitly state that the medical drape comprises micro-channels between the stems along at least a portion of the exterior of the first surface of the backing layer, Crawley et al. state that the backing is water vapor permeable, thereby demonstrating the existence of micro-channels within the material (Col. 3, lines 64-65).

Crawley et al. fail to explicitly state that the medical drape stems comprise an aspect ratio of at least 1.25 – the aspect ratio being dependent on both the height and width of the stems, and that the stems are integrally formed with the backing layer.

Crawley et al. does state, however, that the pattern of dots need not be substantially hemispherical in shape as described by Figs. 1 and 2, and that the pattern of dots may be of any desired shape including shapes such as generally described as squares, rectangles, polygons, etc. Shapes having a pointed or sharp tip, peak, or ridge may also be used for specific applications (Col. 7, lines 18-25). Therefore, it would have been obvious through routine experimentation to one of ordinary skill in the art at the time applicants invention was made to have modified the shape of the dots of Crawley et al., thereby modifying the aspect ratio of the dots such that it exceeds 1.25, depending on the desired application of the material. Furthermore, it would have been obvious to one of ordinary skill in the art at the time applicants invention was made to have modified the size of the dots in Crawley et al. such that the aspect ratio exceeds 1.25, since such a modification would have involved a mere change in the size of a component. A change in size

is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). The obviousness of these aforementioned modifications is further supported in the equivalent teachings of Lindquist et al. (see Fig. 5; Col. 2, lines 59-68; Col. 5, lines 13-26).

Furthermore, even in the absence of modifying Crawley et al. based on its own teachings, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have modified the aspect ratio of the stems such that the aspect ratio is at least 1.25 since it was notoriously well known in the art at the time Applicant's invention was made to provide backing layers with integrally connected stem portions with aspect ratios exceeding 1.25 as evidenced by WO '775 (see Figs. 5-11; p.11, lines 4-6 –"the protrusions may be rod-like with a height of from about 1mm to about 2cm with a diameter of about 1mm to about 2cm"). WO '775 teaches the use of the aforementioned aspect ratio for the purpose of providing an improved frictional surface that exhibits an ability to frictionally engage a surface on an opposing article (see Abstract). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have combined the teachings of Crawley et al. and WO '775 since each of the aforementioned references are analogous insofar as being directed at substrates comprising frictional surfaces.

Therefore, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have modified the aspect ratio of the stems in Crawley et al. either based on the teachings in Crawley et al. alone or in combination with WO '775 in order to provide stems integrally connected with the backing layer that exhibit an improved frictional surface that exhibits the ability to frictionally engage a surface on an opposing article. With

regards to the stems being integrally connected to the backing member, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have modified the two layers in Crawley et al. integral (based on the teachings of Crawley et al. alone or in combination with WO '775) since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Although the Applicant's contend that such a modification would destroy the moisture permeability function of Crawley et al., the Examiner respectfully disagrees. As demonstrated in Fig. 2 of Crawley et al., a grid-like pattern is formable such that the backing layer is still breathable (Col. 7, lines 2-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to have integrally connected the stems while still leaving areas free of elastomeric projections, thereby continuing to provide a moisture permeable substrate.

3. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al. ('707) in view of WO '775 and Lindquist et al. ('359), and further in view of Lind et al. (#4,204,532).

Crawley et al., WO '775, and Lindquist et al. teach a medical drape structure as detailed above. The aforementioned prior art fails to teach a reinforcing layer disposed between the first and second backing layers.

Lind et al., however, teach a surgical drape with a non-skid fenestration material layer (See Abstract). Lind et al. teach a fenestration material with a scrim reinforcement that can be either woven or non-woven. Lind et al. provide the fenestration structure for the purpose of improving instrument retaining and non-skid characteristics while eliminating the undesirable

absorbency characteristics of prior art (Col. 1, lines 42-47) as well as to provide a material that can withstand sterilization techniques utilized for materials having medical applications (Col. 4, lines 51-54). It would have been obvious through routine experimentation to one of ordinary skill in the art at the time applicant's invention was made to have used a reinforcement fenestration structure between the base material layers of a medical drape structure for the purpose of improving the instrument retaining, non-skid, and absorbency characteristics of the drape as well as to provide a material that can withstand the sterilization techniques utilized for materials having medical applications as taught by Lind et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have modified the aforementioned prior art to include a reinforcement fenestration structure between the first and second base layers as taught by Lind et al. in order to improve the instrument retaining, non-skid, and absorbency characteristics of the drape as well as to provide a material that can withstand the sterilization techniques utilized for materials having medical applications.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al. ('707) in view of WO '775 and Lindquist et al. ('359), and further in view of Chen (#3,972,328).

Crawley et al. teach a medical drape as described above. Crawley et al. fail to teach the addition of an antioxidant to the elastomeric material of the drape.

Chen, however, teaches a surgical bandage that comprises an antioxidant (butylated hydroxytoluene or butylated hydroxyanisole) for the purpose of prolonging the shelf life of the bandage (Col. 2, lines 3-7 and lines 44-48). It would have been obvious through routine experimentation to one of ordinary skill in the art at the time applicant's invention was made to

have used an antioxidant along with the elastomeric material of a medical drape for the purpose of prolonging the shelf life of the drape as taught by Chen.

Therefore, it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have modified Crawley et al. to include antioxidants in the elastomeric material of the medical drape as taught by Chen in order to prolong the shelf life of the drape.

Response to Arguments

5. Applicant's arguments with respect to claims 1-3, 5-20, and 23-24 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner notes that the claim objection from the previous office action has been withdrawn pursuant to the Applicant's amended claims.

With regards to the Applicant's contentions regarding the use of a fenestration material as a reinforcing layer, the Examiner respectfully disagrees. Although a fenestration is known in the art to be an opening that provides access to a body for a surgeon to perform surgery, the term fenestration material is directed at the material layer surrounding the opening. Therefore, the Examiner maintains that it would have been obvious to use the fenestration material as disclosed by Lind et al. to provide a reinforced area of the medical drape.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian P. Egan whose telephone number is 703-305-3144. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Brian P Egan 12/17/03
BPE

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

12/22/03